

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form ([see an example](#)) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below. Some articles will have been accepted based in part or entirely on reviews undertaken for other BMJ Group journals. These will be reproduced where possible.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Herbal medicines for the treatment of acute otitis media: Protocol for a systematic review
AUTHORS	Son, Mi-Ju; Kim, Yun Hee; Kim, Young-Eun; Lee, Hye Won; Lee, Myeong Soo

VERSION 1 - REVIEW

REVIEWER	Levi, Jessica Boston University, Otolaryngology/Head & Neck Surgery
REVIEW RETURNED	25-Sep-2013

GENERAL COMMENTS	This is a great description of a system that will be used to analyze CAM for otitis media. The authors have clearly thought of many situations they will encounter that will make the analysis more difficult and have addressed these and provided solutions. I am curious if there are other ways in which the analyses will be limited. I am looking forward to reading the final product
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REVIEWER	Lee, Donghyo / D.K.M. & Ph.D. Assistant Professor, College of Korean Medicine, Woosuk University, Republic of Korea I certify that there is no conflict of interest.
REVIEW RETURNED	26-Sep-2013

THE STUDY	<p>The topic is certainly of interest and is timely. But there are several points that need attention.</p> <p>1. Description of the condition: 1) More details on the condition, such as complications, are needed. 2) Socio-economic costs of AOM need additional explanation in the manuscript.</p> <p>2. Description of the intervention: The topic of this review is "herbal medicine", isn't it? But, there is nothing to describe about herbal medicine.</p> <p>3. How the intervention might work: 1) This paragraph does not seem relevant to the understanding of the pathophysiology of herbal medicine for AOM. 2) Although the authors mentioned about the results of experimental or clinical research, more information should be provided thus the reader can understand the evidence.</p> <p>4. Objectives:</p>
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	<p>This sentence is vague. The words 'efficacy' and 'effectiveness' are interchangeable in most situations. However, the difference between 'efficacy' and 'effectiveness' when it comes to medicines is subtle but important.</p> <p>5. Types of studies: RCTs are considered the gold standard study design to investigate the effect of health interventions. However, in some situations like CAM, non-RCTs or well-designed observational studies may provide an alternative to obtain estimates of treatment effect.</p> <p>6. Type of interventions: The criteria of conventional therapy for AOM should be explained.</p> <p>7. Inclusion criteria: It might be better to present the criteria including item such as 'quasi-randomized trials'.</p> <p>8. Assessment of risk of bias in the included studies: Quasi-randomized trials will be assessed by MINORS or RoBANS? Or those will not be assessed?</p> <p>9. Subgroup analysis and the investigation of heterogeneity: More details on the causes of heterogeneity should be considered as follows: Combined treatment (herbal medicine used alone or as a combined therapy of herbal medicine with a conventional therapy), the dose of herbal medicine, or study type.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer : Jessica Levi

This is a great description of a system that will be used to analyze CAM for otitis media. The authors have clearly thought of many situations they will encounter that will make the analysis more difficult and have addressed these and provided solutions. I am curious if there are other ways in which the analyses will be limited. I am looking forward to reading the final product

Answer> Thank you for your comment.

Reviewer : Lee, Donghyo / D.K.M. & Ph.D.

I certify that there is no conflict of interest. The topic is certainly of interest and is timely. But there are several points that need attention.

Comment 1) More details on the condition, such as complications, are needed.

Revised> We have now added more details in page 5 as highlighted.

Comment 2) Socio-economic costs of AOM need additional explanation in the manuscript.

Revised> We have now added more details in page 5 as highlighted.

Comment 3) The topic of this review is "herbal medicine", isn't it? But, there is nothing to describe about herbal medicine.

Revised> We have now added the description for herbal medicine (pages 6, line 1-3)

Comment 4) This paragraph does not seem relevant to the understanding of the pathophysiology of herbal medicine for AOM. Although the authors mentioned about the results of experimental or clinical

research, more information should be provided thus the reader can understand the evidence.

Revised> We have re-written the paragraph “How the intervention might work”(pages 6, line 7-12).

Comment 5) This sentence is vague. The words ‘efficacy’ and ‘effectiveness’ are interchangeable in most situations. However, the difference between ‘efficacy’ and ‘effectiveness’ when it comes to medicines is subtle but important.

Revised> We use we will include only randomized controlled trials. We have now changed the term ‘effectiveness’ to ‘efficacy’.

Comment 6) RCTs are considered the gold standard study design to investigate the effect of health interventions. However, in some situations like CAM, non-RCTs or well-designed observational studies may provide an alternative to obtain estimates of treatment effect.

Revised> We agree with your comment. However, we have now decided to include only RCT for elucidate many possible potential bias for evidence. If we cannot find any RCT, then we discuss the other type of design for further evidence.

Comment 7) The criteria of conventional therapy for AOM should be explained

Revised> We have added the sentence.(page 7, line 23-25)

Comment 8) It might be better to present the criteria including item such as ‘quasi-randomized trials’.

Revised> We have changed the sentence. (pages 9, line 23)

Comment 9) Quasi-randomized trials will be assessed by MINORS or RoBANS? Or those will not be assessed?

Revised> We have decided to use Cochrane Risk of Bias.

Comment 10) More details on the causes of heterogeneity should be considered as follows:

Combined treatment (herbal medicine used alone or as a combined therapy of herbal medicine with a conventional therapy), the dose of herbal medicine, or study type.

Revised> We have added more details. (pages 12, line 22-23)

Thank you for your valuable comments.